JUL 2 3 2003

510(k) Summary for
Emit® II Plus Cocaine Metabolite Assay

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K031512

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer:	Syva Company – Dade Behring Inc. 20400 Mariani Ave Cupertino, CA 95014
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Kathleen Dray-Lyons Tel: 781-826-4551 Fax: 781-826-2497
Preparation date:	July 14, 2003

2. **Device Name/ Classification:**

Emit® II Plus Cocaine Metabolite Assay:	Cocaine and cocaine metabolite test system Class II (862.3250)
Product Code:	91 DIO

3. **Identification of the Legally Marketed Device:**

Emit® II Plus Cocaine Metabolite Assay (K993988)

4. **Device Description:**
Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay for qualitative and semi-quantitative analysis of cocaine metabolite (benzoylecgonine) in human urine.

5. Device Intended Use:

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff (SAMSHA initial test cutoff level). The assay is intended for use in the qualitative and semi-quantitative analyses of benzoylecgonine (cocaine metabolite) in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Monoclonal Cocaine Metabolite Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

6. Medical device to which equivalence is claimed and comparison information:
The modified Emit® II Plus Cocaine Metabolite Assay is substantially equivalent in intended use to the Emit® II Plus Metabolite Assay currently marketed. The modified Emit® II Plus Metabolite Assay, like the current Emit® II Cocaine Metabolite Assay is intended to be used for the qualitative and semi-quantitative analyses of cocaine metabolite (benzoylecgonine) in human urine.

7. Device Performance Characteristics:

Method Comparison:

Qualitative Results

150 ng/mL CUTOFF

		Reference Method (GC/MS)	
		+	-
Emit® II Plus Cocaine Metabolite Assay	+	62	2 *
	-	7 **	54

Percent agreement: 93%
* GC/MS results were 123 and 140 ng/mL
** GC/MS results were 150, 151, 157, 162, 164, 166, and 190 ng/mL

300 ng/mL CUTOFF

		Reference Method (GC/MS)	
		+	-
Emit® II Plus Cocaine Metabolite Assay	+	34	6 *
	-	1 **	84

Percent agreement: 94%
* GC/MS results were 218, 241, 261, 294, 295, and 298 ng/mL
** GC/MS result was 354 ng/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 3 2003

Ms. Kathleen Dray-Lyons
Manager Regulatory Affairs and Compliance
Syva Co., Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714

Re: k031512
Trade/Device Name: Emit® II Plus Cocaine Metabolite Assay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and Cocaine Metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: May 12, 2003
Received: May 14, 2003

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Emit® II Plus Cocaine Metabolite Assay

Indications for Use:

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K031512

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)